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Nos. 80-2182, 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

REPLY TO PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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Question Presented

1. Did the Court of Appeals err in holding the petitioners, who are manufacturers and distributors of prescription drugs sold in capsules which deliberately simulated the appearance of the respondent's drug capsules, liable for contributory infringement of the plaintiff's registered trademark where there was undisputed evidence that the look-alike capsules had been illegally dispensed by pharmacists and labelled with the respondent's trademark; that a series of pharmacy shoppings in New York State showed that 29% of the prescriptions filled with the look-alike capsules are mislabelled with respondent's trademark; that the simulating of the appearance of respondent's capsules makes illegal substitution and undetected mislabelling easier; that there is no legitimate functional reason for copying the colors; and that the petitioners, in selling their capsules, among other things, emphasize that the colors of their capsules are the same as those of plaintiff?

Statement Pursuant to Supreme Court Rule 28.1

Respondent Ives Laboratories, Inc. (hereinafter "Ives") is a subsidiary of American Home Products Corporation, which also has numerous other subsidiaries.

Two petitions for certiorari, one on behalf of Inwood Laboratories, Inc. and Premo Pharmaceutical Laboratories, Inc. and one on behalf of the other defendants, have been filed. This response is filed in opposition to both petitions.

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Respondent.

REPLY TO PETITIONS FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Statement of the Case

Ives has for many years manufactured and sold a prescription drug product known by the generic name cyclandelate. It has identified this cyclandelate by using its registered trademark CYCLOSPASMOL and by selling the drug, which is a white powder, in distinctive blue and blue/red capsules. The petitioners, and defendants below, are all manufacturers and distributors of generic cyclandelate which they sell in blue and blue/red capsules copying the appearance of the Ives' capsules. The copying was admittedly deliberate. In filling prescriptions, pharmacists have illegally substituted the look-alike generic capsules

for CYCLOSPASMOL cyclandelate and have passed off the generic look-alike for CYCLOSPASMOL by showing plaintiff's trademark on the labelling of the capsules dispensed.

Ives does not seek to enjoin the sale of the drug cyclandelate. It has brought no action against a competitor selling the product in a capsule that does not copy the appearance of Ives' capsules. Rather, it has alleged in this case that the sale of the product in look-alike capsules constitutes a false designation of origin under Section 43(a) of the Lanham Act and unfair competition under New York law. It has also charged that the defendants are liable for contributory infringement of Ives' trademark, in violation of Section 32 of the Lanham Act, 15 U.S.C. §1114.

At trial, Ives introduced substantial evidence in support of its claims under §43(a) of the Lanham Act and New York's law of unfair competition, including a survey which established that patients associate the capsule colors blue and blue/red with CYCLOSPASMOL and that 70% of those patients interviewed, when shown the defendants' look-alike capsules, misidentified them as plaintiff's product CYCLOSPASMOL.* The Court of Appeals decided that the defendants were liable for contributory trademark infringement, and thus did not reach these other claims.

From the outset, the District Court took a very narrow and restrictive view of all aspects of the applicable law. In denying Ives' Motion for Preliminary Injunction it held, on the issue of contributory infringement, that plaintiff had failed to show that the defendants "have conspired with the pharmacists or suggested that they disregard the doctors' orders." (13a) The Court noted that mislabelling

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* This represents combined misidentification for both the blue and blue/red capsules, aided and unaided.

would subject a pharmacist to criminal and civil penalties. Although acknowledging that use of the blue and blue/red capsules "may make discovery of the offense less likely" it held that this "scarcely justified holding defendants as accessories to the crime." (13a) It interpreted the law of contributory infringement as extending only to those who actively share a retailers' infringement. (13a)

Although affirming the denial of a preliminary injunction as being within the discretion of the District Court, the Court of Appeals on the first appeal, in a decision written by Judge Friendly, corrected numerous errors of law of the lower court. On the issue of contributory infringement, it first noted that the most serious act of wrongdoing by pharmacists occurs where CYCLOSPASMOL has been prescribed, but the pharmacist illegally substitutes the look-alike cyclandelate and mislabels it as CYCLOSPASMOL. A wrong characterized by Judge Friendly as "intermediate" occurs when the prescription permits substitution and the druggist fills it with defendants' product, but names it CYCLOSPASMOL, an act "clearly actionable against the druggist". (34a)

The Court of Appeals, on the first appeal, held that, while these wrongdoings may be actionable under the New York Education Law, that law does not displace the protection for competitors embodied in trademark and unfair competition law. It noted that the District Court's reading of applicable law was too narrow, and was erroneous (35a):

> "... a manufacturer or wholesaler would be liable under §32 if he suggested, even if only by implication, that a retailer fill a bottle with the generic capsules and apply Ives' mark to the label, or continued to sell capsules containing the generic drug which facilitated this to a druggist whom he knew or had reason to know was engaging in the practices just described."

The Court also accepted as the "proper criteria" those stated in *Coca-Cola Co.* v. *Snow Crest Beverages, Inc.*, 64 F.Supp. 980, 989 (D. Mass. 1946), aff'd 162 F.2d 280 (1 Cir. 1947), cert. denied, 332 U.S. 809 (1947) in which it was held that a manufacturer's accountability for infringement committed by its customers (64 F.Supp. at p. 989):

> "... turn(s) on the issue whether a reasonable person in the defendant's position would realize either that he himself had created a situation which afforded a temptation to or an opportunity for wrong by l'homme moyen sensuel or was dealing with a customer whom he should know would be peculiarily likely to use the defendant's product wrongfully."

Judge Friendly held that, if the District Court judge "considered a narrower view of the doctrine of contributory infringement to be warranted because mislabeling by a New York pharmacist 'would put him at risk of criminal and civil penalties and would subject him to the loss of his license' and thought that defendants would be liable for contributory infringement only if they could be held 'as accessories to the crime' he was in error." (35a) The petitioners herein have not claimed that the first decision of the Court of Appeals was erroneous.

At trial there was substantial uncontradicted evidence that pharmacists had passed off the look-alike cyclandelate capsules as Ives' CYCLOSPASMOL capsules. There were fifteen instances in which shoppings at pharmacies showed illegal substitution of the generic, with thirteen of the bottles being then labelled CYCLOSPASMOL.* It was

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* Although the defendants downplay this evidence as not being substantial, the Court of Appeals noted that "it was surprising that Ives was able to produce as many such instances as it did." (81a)

also proved that a pharmacist in Ohio had put unmarked look-alike capsules into single dosage unit packs which he then individually mislabelled CYCLOSPASMOL or CYCLANDELATE CYCLOSPAZMOL. [sic] There was also substantial evidence of the "intermediate" wrongdoing described by the Court of Appeals on the first appeal. Ives had a series of random pharmacy shoppings done at 83 pharmacies in New York State which showed that, of the 35 pharmacies dispensing the generic look-alike in filling a "substitution permissible" prescription, 29% mislabelled the product using plaintiff's CYCLOSPASMOL trademark. Contrary to the assertions in petitioner's briefs, the pharmacists were not merely making a fair descriptive use of the trademark.* Statistical evidence showed that the results of those shoppings were projectible on a statewide basis.

In addition, one of the defendants, Premo Pharmaceutical Laboratories, Inc. (hereinafter "Premo") did shoppings in 25 pharmacies and produced two instances in which the labels on generic cyclandelate wrongly showed the trademark CYCLOSPASMOL. Ives also did a survey to establish that patients associate the blue and blue/red capsule colors with CYCLOSPASMOL. In 9 of 17 instances where the patients interviewed at home produced their medicine bottles to the interviewer during the survey interviews, the bottles contained generic cyclandelate, but the labels erroneously identified the product as CYCLOSPASMOL.

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* The ten labels (which petitioners Darby Drug Co., Inc., et al. acknowledge at page 9 of their petition to be examples of mislabelling) show: CYCLOSPASMOL: Generic Cyclospasmol; Cyclospasmol (Gen); Cyclospasmol; Cyclospasmol Generic; Cyclospasmol 400 ETE(Rugby); Generic Cyclospasmol; Cyclospasmol; and Cyclospasmol.

An officer of the defendant Inwood Laboratories Incorporated (hereinafter "Inwood") acknowledged that he knew of the existence of the practice of illegal substitution. Inwood and Premo had both been defendants in other cases in which illegal substitution was proved. The defendants admitted that the duplication of color of the capsules made such illegal substitution easier, or less readily detectable. As the president of Premo stated, "it's obvious if a man is going to do something illegal like pass off counterfeit money, it's easier if he has a good imitation."

In addition to furnishing look-alikes, defendants have emphasized in their promotional materials that their cyclandelate is in blue or blue/red capsules, and have put their generic products on lists juxtaposed with lists of the branded drugs copied, including CYCLOSPASMOL. A witness for the defendants, who was employed by a generic distributor, then a defendant in another look-alike case, testified that furnishing lists of generics and brand names makes it easier for the pharmacist with larceny in his heart.

The District Court, despite this showing, held that contributory infringement had not been proved. Despite the admonition in the opinion of Judge Friendly, it again emphasized that a pharmacist guilty of illegal substitution is subject to both civil and criminal penalties under New York law. (69a) It excused the mislabelling by holding, without the benefit of testimony or evidence, that the druggists "appear not deliberately to have been attempting to pass off the generic product as Cyclospasmol but rather to have misunderstood the precise requirements of the New York Drug substitution law." (60a) The Court also noted that most pharmacists who had mislabelled informed the customer that a generic drug was being dis-

pensed. The evidence, as noted by the Court of Appeals, however, was that they informed them not as a matter of course but only because the shopper, pursuant to instructions from the designer of this survey, had specifically inquired about this after having received the drug from the pharmacist. (80a)

The Court of Appeals, in reversing this decision, held that contributory infringement had been proved (80a):

> "We believe that the district court, in considering Ives' §32 claim, erred upon remand in declining to give any weight to additional evidence offered by Ives indicating that appellees' use of identically-colored, look-alike drug capsules assisted druggists in labeling generic cyclandelate as Ives' trademarked product CYCLOSPASMOL, and that they could reasonably anticipate that the use of these capsules would have such an effect."

It noted particularly the substantial additional evidence of "intermediate" cases of contributory infringement, and characterized the pharmacy shoppings done in New York State as having been carried out in a rigorous, impartial manner. (81a) The pattern of mislabelling disclosed by those shoppings "is precisely the sort of showing which we held would be probative of plaintiff's §32 claim." (82a)

The Court held that this evidence "was clearly sufficient to establish a §32 violation" (82a):

> "By using capsules of identical color, size and shape, together with a catalog describing their appearance and listing comparative prices of CYCLOSPASMOL and generic cyclandelate, appellees could reasonably anticipate that their generic drug product would by a substantial number of druggists be substituted illegally

> for Ives' trademarked CYCLOSPASMOL or that bottles of their lower-priced product might be mislabeled as CYCLOSPASMOL, all to the druggists' economic advantage. This amounted to a suggestion, at least by implication, that the druggists take advantage of the opportunity to engage in such misconduct. By using look-alike capsules, appellees also reduced the likelihood that patients who were given a generic substitute would bring that fact to their doctor's (or their druggist's) attention."

The Court cited several cases in which similar conduct had been enjoined, all involving prescription drugs. It noted that the District Court conclusion that the mislabelling in the pharmacy shopping was the result of mistake on the part of the pharmacists had no support in the record. No witnesses or surveys supporting the District Court's suggestion were ever introduced at trial. (83a)

The Court of Appeals also held that the appropriate relief was to enjoin use of the look-alike capsules and require that different colors be used (86a):

> "This would alert the patient to the possibility that he has been given cyclandelate when his doctor specifically prescribed CYCLOSPASMOL, as well as put him on notice that the lower generic cost of the cyclandelate should have been charged if that is in fact what he has received. Such a change could be made by appellees without any appreciable difficulty or expense."

In this context, the nature of the product—a prescription drug sold in small, colored capsules—becomes important. The product is prescribed principally to the elderly, and

markings on the capsules are unlikely to be noticed.* In fact, generic cyclandelate capsules bearing the imprint "Premo" were passed off as CYCLOSPASMOL by one pharmacist. Thus, Judge Friendly noted, on the first appeal, that "it is significant that, given the method of sale, Ives had no way of identifying Cyclospasmol to the ultimate consumer other than by the color of the capsule and by the imprint on it, which is contended to be of dubious value." (51a)**

Judge Friendly had also held that "one would not initially suppose the color of a capsule to be functional. Unlike the chocolate in the *Warner* case, the blue and blue-and-red coatings of Ives' capsules do not contribute to their efficacy; any other colors would do as well. The argument that, like functional elements, color ought to be automatically denied protection because of the risk of creating monopolies through tying up all available colors . . . does not seem persuasive; the evidence showed that, in addition to the other primary colors, an endless number of color combinations was available to the defendants." (50a)

Substantial evidence to reinforce this holding was introduced at trial. There was uncontradicted testimony that, when chosen by Ives, the blue and blue/red colors were completely arbitrary. The colors were not a feature disclosed or claimed in the patent. There was no suggestion

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* When first sold, the defendants' blue and blue/red capsules showed no imprint at all. Even the executives of the various defendants, after having examined the capsules, were unable to identify their particular's company's drug.

** The District Court, after trial, concluded that putting warning statements on the defendants' packages, as sold to pharmacists, would not be likely to deter deliberate and fraudulent substitution by the pharmacists. (61a) On the appeal, this was not challenged by the defendants.

in the record that the colors were medically necessary or were chosen to contribute to the therapy offered by the cyclandelate contained in the capsules, nor do the capsules themselves, which are made of gelatin, contribute to the therapeutic effect. Indeed capsules are not even necessary in dispensing cyclandelate, which is also sold in tablet form.

Displays from capsule manufacturers were introduced to show the many thousands of other color combinations that could have been selected for this or any other prescription product. There was also testimony that one competitor, W.E. Hauck Inc., sells cyclandelate in a non-look-alike all red 200 mg. capsule and had done so for at least two years.

Ives also introduced uncontradicted evidence and exhibits showing that, in numerous instances, in the case of prescription drugs for both acute and long-term therapy, color duplication is not necessary; the same products, in the same dosage forms, but in numerous different colors are available. For example, the most widely prescribed vasodilator, papaverine hydrochloride, which is taken for the same therapeutic uses as cyclandelate, comes in the same dosage form but in many different colors. Numerous colors are available, even for those drugs used in treating patient anxiety. And, the evidence showed that institutions purchasing drugs make decisions based on price, not color.

Reasons for Denying Certiorari

Petitioners have put forth no considerations that would justify the granting of certiorari. Neither the decision below, nor the record, raises the exaggerated questions of free speech, monopoly, and public policy as presented in the petitions.

I.

The Court of Appeals Decision Finding Defendants Liable for Contributory Infringement Is Consistent With Other Applicable Case Law and Presents No Questions Which Should Be Reviewed by This Court.

While the petitioners urge that the Court's decision effects a radical change in the law of trademarks, in fact it is completely consistent with applicable law. Petitioners furnished the look-alike capsules, the instrument of fraud that enabled pharmacists to illegally substitute and mislabel without detection. It is well established that a defendant's accountability under this doctrine does not require active participation in the actual infringement. Rather, it depends on whether a reasonable person in the defendant's position would realize that he had created a situation which afforded a temptation to or an opportunity for wrong, *Andrew Jergens Co.* v. *Bonded Products Corp.*, 21 F.2d 419, 424 (2 Cir. 1927), cert. denied, 275 U.S. 572 (1928); *Union-Carbide Corp.* v. *Ever-Ready, Inc.*, 531 F.2d 366, 384 (7 Cir. 1976), cert. denied, 429 U.S. 830 (1976). If passing off is foreseeable or may be reasonably anticipated, then the manufacturer is liable, *Stix Products, Inc.* v. *United Merchants & Manufacturers, Inc.*, 295 F. Supp. 479, 496 (S.D.N.Y. 1968); *Stewart Paint Mfg. Co.* v. *United Hardware Distributing Co.*, 253 F.2d 568, 575 (8 Cir. 1958). The wrong lies in "designedly enabling the dealers to palm off the preparation as that of the respondent", *William R. Warner and Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 530 (1924).

This is not a situation, as urged by petitioners Inwood and Premo, in which liability was based on their truthful comparative advertising, nor did the Court so hold. The defendants did more than disclose information about their

generic cyclandelate products. Defendants sold those products in a trade dress, blue and blue/red capsules, simulating the appearance of plaintiff's capsules; they emphasized the color identity in their catalogs; and they provided lists of their products on which there were shown, in juxtaposition, the trademarks of the market innovators copied, including Ives' CYCLOSPASMOL.

Historically, it has been held that, by the use of such tactics, manufacturers created too great a temptation for illegal substitution, *Smith, Kline & French* v. *Heart Pharmaceutical Corp.*, 90 F.Supp. 976 (S.D.N.Y. 1950); *E.R. Squibb & Sons, Inc.* v. *Premo Pharmaceutical Labs, Inc.*, 195 U.S.P.Q. 545 (S.D.N.Y. 1977); *Merrell-National Laboratories, Inc.* v. *Zenith Laboratories, Inc.*, 194 U.S.P.Q. 157 (D.N.J. 1977), aff'd on procedural grounds, 579 F.2d 786 (3 Cir. 1978). The decision of the Court of Appeals is also consistent with a recent series of cases, also involving the sale of look-alike generic drugs, in which the practice of furnishing such an instrument of deception was enjoined. Although the cases were decided under Section 43(a) of the Lanham Act, or under general theories of unfair competition, they are nonetheless directly pertinent.

In *A.H. Robins Co.* v. *Medicine Chest Corp.*, 206 U.S.P.Q. 1015, 1019 (E.D. Mo. 1980), defendants were enjoined from selling a generic drug in look-alike blue tablets. It was held, in relevant part:

> "Anyone who puts goods into the hands of dealers for sale to the public which contain the means for deceiving purchasers, and/or which can be reasonably anticipated to so deceive, is subject to an injunction against the further provision of these means to eliminate their unfair competition against the goods of another which has been or is likely to be engaged in by the dealers on this basis. Thus, defendants Inwood,

Schein, and Spencer-Mead can be held liable for putting their products into various dealers' hands, such as defendant-pharmacists, if they can reasonably anticipate that their goods may be passed off as goods of another, whether or not they conspired with the dealer or intend the substitution of the goods involved.

• • •

"By intentionally simulating the size, shape, and color of Robins' product to enable them to sell their own products; by appropriating a significant portion of Robins' registered trademark, "DIMETAPP"; by making unsupported and unverified claims of equivalency; by emphasizing the color which the parties' products have in common; and by stressing the difference in price between the parties' products, Inwood, Schein, and Spencer-Mead have created a situation in which they knew or should have anticipated that such would result in illegal substitution of their drug for that of plaintiff."

The Court of Appeals for the Third Circuit, in *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1062 (3 Cir. 1980), likewise found that the defendant's conduct in selling a look-alike prescription drug capsule was actionable since it put the maroon and white capsule, "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product *even if the manufacturer does nothing else to encourage passing off*." (emphasis supplied) In *Boehringer-Ingelheim G.m.b.H.* v. *Premo Pharmaceutical Laboratories, Inc.* (D.N.J. Docket No. 79-0358, September 24, 1980), it was also held that defendants facilitated passing off by pharmacists "of generic dipyridamole as Persantine by copying Persantine's trade dress" (small orange tablets).

II.

The Court of Appeals Decision Does Not Involve Any Infringement of Free Speech.

Two of the six defendants petitioning for certiorari argue that the Court's finding of liability conflicts with their First Amendment right of free speech. The other four petitioners make no such argument, and it has never been raised before in this case.

While commercial speech is protected by the First Amendment, there is no obstacle to imposing liability for commercial speech that is deceptive or misleading, *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). And, the copyright laws are enforced although they, too, may be considered to inhibit free speech, *Zacchini* v. *Scripps-Howard Broadcasting Co.*, 433 U.S. 562, 576 (1977). Under similar theories, those who copy the trademarks or the colored trade dress of an innovator may also be enjoined without violating First Amendment rights, *Dallas Cowboys Cheerleaders, Inc.* v. *Pussycat Cinema, Ltd.*, 604 F.2d 200, 206 (2 Cir. 1979):

> "Nor does any other first amendment doctrine protect defendants' infringement of plaintiff's trademark [its cheerleaders' uniform]. That defendants' movie may convey a barely discernible message does not entitle them to appropriate plaintiff's trademark in the process of conveying that message. . . ."

In any event, the First Amendment argument in the present case is completely specious, and appears to have been raised solely to capture the Court's attention in the hope that certiorari would be granted. The decision of the Court

did not, as urged by two of the six petitioners, prevent them from adequately and accurately describing their generic products to their customers. The petitioners forget that the principal wrong was their furnishing of cyclandelate in look-alike capsules. References to their colors, and to plaintiff's trademark and the price differential between plaintiff's products and those of the petitioners merely served to aggravate that principal wrong and make it more likely that illegal substitution and mislabelling would occur. Petitioners have no First Amendment right to copy the trade dress of the Ives' product. Yet that is the only conduct enjoined. Petitioners have included in the Appendix herein the Order of the District Court entered pursuant to the mandate of the Court of Appeals. The injunction covers only the sale of look-alike capsules and does not in any way restrict any commercial speech of the defendants or inhibit what they may say truthfully in their further sale of generic cyclandelate. (102a-104a)

III.

The Court of Appeals Decision, While Protecting the Colors of Plaintiff's Capsules, Does Not Thereby Create a Monopoly in the Sale of Cyclandelate.

The decision of the Court of Appeals is also not in conflict with prior decisions cited by petitioners in which it was held that colors per se were not protectable as trademarks. The cases did not involve prescription drug capsules. As Judge Friendly held on the first appeal, color is the only effective way for Ives to identify its CYCLOSPASMOL capsules to the ultimate consumer. (51a) Cases involving the coloration of ordinary consumer goods are simply not relevant, nor are the two cases involving drug products cited by the petitioners. *Norwich Pharmacal Co.*

v. *Sterling Drug, Inc.*, 271 F.2d 569 (2 Cir. 1959), cert denied, 362 U.S. 919 (1960), was effectively distinguished by Judge Friendly on the first appeal, where he pointed out that this was an over-the-counter medication where the differences in name, labelling and packaging—all seen by the ultimate consumer—were such, that it stretched credulity to imagine a purchaser confusing them, although both were soothing pink stomach remedies. (41a, 51a) And unlike the present case, there was no evidence of passing off or deception.

In *William R. Warner & Co.* v. *Eli Lilly & Co.*, *supra*, p. 11, this Court refused to enjoin the defendant from selling brown colored medication. In that case, the use of chocolate was required in order to make a commercially satisfactory product, i.e., to make the preparation palatable and to act as a suspending medium for the quinine ingredient. The brown color imparted to the finished product was the natural color of the chocolate. Thus, the product necessarily had to be brown. The standard applied by the Court was whether the color, as dictated by the presence of the chocolate ingredient. "serves a substantial and desirable use" and is essential to the manufacture of the product. (265 U.S. at p. 531)

Under this standard, the blue and blue/red colors are certainly not functional. As Judge Friendly noted on the first appeal, there were thousands of other colors to select from; the selection of blue and blue/red was completely arbitrary. The ingredients in the drug are white. He also held that any evidence of functionality would have to depend on the showing defendants were able to make at trial. (50a) While the District Court held that the colors were functional, the Court of Appeals held that they were not, specifically finding the defendants' proof on this point to

be "unconvincing". "Appellees have not offered *any persuasive evidence* of a legitimate reason" to sell look-alike capsules. (84a) (emphasis supplied) Petitioners urge that the appellate decision should not be upheld because, in the opinion, Judge Mansfield did not specifically state that the District Court's findings on this issue were "clearly erroneous." Since he specifically found the evidence supporting those findings unconvincing and not persuasive, this becomes a matter of semantics. In any event, the question of functionality is one of mixed fact and law, and Judge Mansfield's finding was based not only on what was in the record, but also on the fact that certain evidence had not been introduced, particularly the testimony of patients or a survey of patient attitudes (84-85a):

> "Appellees have not offered any persuasive evidence of a legitimate reason unrelated to CYCLOSPASMOL for using identically-colored, look-alike cyclandelate capsules instead of capsules of a different color, size or shape, which would minimize the practice of mislabeling, illegal substitution or confusion. Their arguments that look-alike capsules reduce patient confusion or anxiety in taking medication, enable doctors to communicate with patients more easily concerning their medication, and aid in their identification of the drug in an emergency situation, are unconvincing. Although a few doctors and one pharmacist were of the view that patients receiving capsules in a size, shape or color different from the medication they usually receive may at first believe that they have the wrong drug, there was no evidence of any instances of such confusion, much less that it was widespread, or that it could not easily be cured by explaining the change to the patient, either voluntarily in accordance with accepted professional practice or in response to the patient's inquiry. . . ."

In any event, given the completely undisputed evidence that other generic drugs are sold in colors that do not duplicate the innovator—including a generic cyclandelate and a leading drug product used for the same therapeutic uses as cyclandelate—the Court of Appeals' conclusion on this issue was the only one reasonably sustainable on the record. It is also completely consistent with numerous other decisions holding that the color of a capsule or tablet is not functional, see e.g., *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13; *A.H. Robins Co.* v. *Medicine Chest Corp., supra* p. 12; *Marion Laboratories Inc.* v. *Michigan Pharmacal Corp.*, 338 F.Supp. 762 (E.D. Mich. 1972), aff'd without opinion, 473 F.2d 910 (6 Cir. 1973).

The decision in *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra,* is particularly pertinent since it involves another recent decision from a different circuit, the Third Circuit, on this question of look-alike prescription drug products. In *SK&F,* the plaintiff sold an oral diuretic in a maroon and white capsule under the trademark DYAZIDE. The defendant began selling a generic version of the drug, also in a maroon and white capsule. Plaintiff moved for a preliminary injunction, alleging violation of §43(a) of the Lanham Act and unfair competition under New Jersey law. In addition to color copying, the plaintiff in that case showed that four pharmacists had illegally substituted the generic look-alike capsules when filling prescriptions for DYAZIDE. The defendant, Premo, raised the same defenses as it raised in the instant case. The District Court granted a preliminary injunction, and was affirmed by the Court of Appeals. It held, in relevant part, that it was reasonable to conclude that Premo's use of a practically identical trade dress would facilitate passing off by pharmacists; that the trade dress had nothing

to do with the purpose or performance of the drug, or with its processing; that *Sears, Compco* did not bar relief; and that there was a violation of Section 43(a) of the Lanham Act and unfair competition under New Jersey law. As in the present case, the defendant there also urged that it could compete more effectively if allowed to continue copying the appearance of the innovator's product. The Court categorically rejected the argument (625 F.2d at p. 1067):

> "In light of these factors, Premo's implausible suggestion that the choice of a maroon and white gelatin capsule was made for functional reasons was not credited by the trial court. Even now it is not enjoined from marketing the combination drug covered by the expired SKF patent in a dosage form different from DYAZIDE. The only answer that Premo made when confronted with these factors was, in essence, that it could compete more effectively in the diuretic market if it could use the same maroon and white capsule color adopted by SKF for DYAZIDE. Probably it could compete better still if it could appropriate the same trade name. But neither appropriation has the look, sound, or feel of equity."

Petitioners also urge that an injunction against the copying of the capsule colors conflicts with the decisions of this Court in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964) and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964). Those cases held that a state could not prevent the copying of an article of merchandise which was, under the federal patent or copyright laws, in the public domain. Thus the drug product, cyclandelate, can be copied. Its trade dress, however, cannot. *Sears* and *Compco* specifically also held that a state could protect businesses in the use of their trademarks, labels, or trade dress. And, this Court has subsequently reconfirmed

the continued viability of the state law of unfair competition, *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470 (1974); *Goldstein* v. *California*, 412 U.S. 546 (1973); *Zachinni* v. *Scripps-Howard Broadcasting Co., supra*, p. 14. As aforesaid, the case does not involve any attempt to restrict the sale of the generic drug cyclandelate, once covered by patent. It involves the distinctive blue and blue/red capsules, or trade dress, in which that drug was sold by Ives.

In any event, the decision at issue finds a violation of federal, not state law, and the rationale of *Sears, Compco* is inapplicable for that reason also, *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13 (625 F.2d at p. 1065). As Judge Friendly held on the first appeal (47a-48a):

> "The opinions can be read as limited to rights claimed under state unfair competition law granting protection equivalent to that of the federal patent or copyright laws for products not enjoying valid patent or copyright protection. The Court, it can be strongly argued, had no need to be concerned with marking out the boundaries of a federal tort over which it had complete control and which Congress could contract if the courts were pressing it further than that body desired."

For the same reason, namely that the decision rests on a federal statute, the arguments of one of the petitioners that it conflicts with New York State public policy is also not apposite.

It is also significant that the plaintiff had additional meritorious claims which the Court did not have to decide, having found liability under §32 of the Lanham Act. Given the Court's finding that the defendants had offered

no convincing evidence of functionality, and the undisputed facts that Ives had long and extensive use of blue and blue/red capsules and that they had been deliberately copied by the defendants, there were alternative grounds, under the reasoning of cases such as *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc., supra* p. 13, for finding liability and enjoining use of the look-alike capsules under §43(a) of the Lanham Act or the law of unfair competition.

In summary, a fair reading of the Court of Appeals opinion shows that this is a classic case of passing off in which the manufacturer or distributor has furnished to the retailer the instrument of fraud enabling the subterfuge to occur without detection. It does not involve any restrictions on comparative advertising; it does not "significantly extend" the doctrine of contributory infringement; it is not a departure from existing trademark law; it does not result in the creation of a monopoly in the sale of the product cyclandelate; it does not have dire consesequences for future competition in the drug industry where other companies sell numerous generic drugs which do not duplicate the appearance of the innovator. Other courts have enjoined the simulation or copying of the appearance of a prescription drug capsule or tablet. The decision is completely consistent with this well established body of case law and with public policy, particularly insofar as it gives patients the ability, because of the color change, to detect illegal substitution and mislabelling and to better police the pricing practices of pharmacists dispensing the generic to assure that cost savings are passed on to the patient.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted,

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Nos. 80-2182, 81-11

IN THE

Supreme Court of the United States

OCTOBER TERM, 1981

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL CO., INC.,

Petitioners,

—against—

IVES LABORATORIES, INC.,

Respondent.

Certificate of Service

I hereby certify that on this day of July, 1981, three copies of the within Reply to Petitions for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit were served by hand on each of the following: Bass, Ullman & Lustigman, Attorneys for Petitioner Inwood Laboratories, Inc., 747 Third Avenue, New York, New York 10017; Kirschstein, Kirschstein, Ottinger & Cobrin, Attorneys for Petitioner Premo Pharmaceutical Laboratories, Inc., 666 Fifth Avenue, New York, New York 10103; and Salon, Marrow & Dyckman, Attorneys for Petitioners Darby Drug Co., Inc., MD Pharmaceutical Company, Inc., Rugby Laboratories, Inc. and Sherry Pharmaceutical Co., Inc., 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

/s/ MARIE V. DRISCOLL

MARIE V. DRISCOLL